

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, Inc.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

IPR2021-00406
U.S. Patent No. 10,716,793

PATENT OWNER SUR-REPLY

TABLE OF CONTENTS

I.	SUMMARY OF ARGUMENT	1
II.	PETITIONER’S REPLY DOES NOT CURE THE PETITION’S FAILURE TO ESTABLISH THE JESC AND JAHA ABSTRACTS AS PRIOR ART	2
A.	Petitioner Has Not Shown that a POSA Exercising Reasonable Diligence Could Have Located the Abstracts.....	3
1.	There Is No Evidence that the Abstracts Were Publicly Accessible at the Respective Conferences	4
2.	Petitioner’s Belatedly Submitted “Date-Stamped” Copies of the Journal Supplements Do Not Prove Public Accessibility, Even If From an “Established ublisher”	6
B.	Petitioner’s “Research Aid” Evidence Likewise Does Not Establish Public Accessibility	9
III.	GROUND 1: PETITIONER’S CALCULATIONS CANNOT SUPPLY THE MISSING 15-90 MICROGRAM DOSE	11
A.	Flawed Assumptions Cannot Supply the Missing Dose	11
1.	A POSA Could Not Infer the Fill Volume In JESC	11
2.	A POSA Could Not Infer the Output Rate in JESC	13
3.	A POSA Could Not Infer the Nebulizer Efficiency In JESC	15
4.	Petitioner Relies on Impermissible Hindsight	17
B.	The POSA Could Not Reliably Calculate A Dose from the '212 Patent.....	17
C.	The References Alone or in Combination Fail To Render the Claims Obvious	19

1.	Petitioner’s Calculations Fail Because They Do Not Address Non-Linearity.....	20
2.	No Motivation to Combine with A Reasonable Expectation of Success	21
3.	The Prior Art Does Not Disclose a “Therapeutically Effective” Single Event Dose According to Dr. Hil.....	22
IV.	GROUND 2: PETITIONER’S REPLY DOES NOT CURE THE DEFECTS IN ITS PETITION	23
V.	FOUNDATIONS 3-6: PETITIONER’S REPLY FAILS TO ADDRESS GHOFrani OR VOSWINCKEL 2006	25
VI.	SECONDARY CONSIDERATIONS REBUT PETITIONER’S GROUNDS.....	25
VII.	CONCLUSION	26

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>In re Cyclobenzaprine Hydrochloride</i> , 676 F.3d 1063 (Fed. Cir. 2012)	26
<i>Endo Pharms. Sols., Inc. v. Custopharm Inc.</i> , 894 F.3d 1374 (Fed. Cir. 2018)	20, 24
<i>Intelligent Bio-Systems v. Illumina Cambridge</i> , 821 F.3d 1359 (Fed. Cir. 2016)	3
<i>In re Klopfenstein</i> , 380 F.3d 1345 (Fed. Cir. 2004)	4
<i>Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc.</i> (Fed. Cir. 2021).....	21
Statutes	
35 U.S.C. § 102(b)	2, 10

EXHIBIT LIST

Exhibit	Description
EX2001	Declaration of Dr. Aaron Waxman
EX2002	Dr. Waxman's <i>curriculum vitae</i>
EX2003	Declaration of Dr. Werner Seeger
EX2004	Declaration of Dr. Hossein A. Ghofrani
EX2005	Declaration of Dr. Frank Reichenberger
EX2006	Declaration of Dr. Friedrich Grimminger
EX2007	Tyvaso Orange Book listing
EX2008	Hill, N., 2005, <i>Therapeutic Options for the Treatment of Pulmonary Hypertension</i> , Medscape Pulmonary Medicine 9(2).
EX2009	Substantive Submission filed in 12/591,200 (Mar. 9, 2015)
EX2010	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-1 (public docket)
EX2011	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-11 (public docket)
EX2012	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-16 (public docket)
EX2013	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), unnumbered docket entry dated 7/30/2020
EX2014	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-20 (public docket) (excerpted)
EX2015	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-29 (public docket)
EX2016	<i>United Therapeutics Corporation v. Liquidia Technologies, Inc.</i> , Case No. 1:20-cv-00755-RGA-JLH (D. Del.), ECF-45 (public docket)

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.